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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,078

04/01/2005

Mark Manasas

FIW-002.01

7458

25181

7590

03/27/2008

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EXAMINER

BOGART, MICHAEL G

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

03/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,078	<b>Applicant(s)</b> MANASAS ET AL.	
	<b>Examiner</b> MICHAEL G. BOGART	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 25-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/01/2005</u> .                                              | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election without traverse of claims 1-24 in the reply filed on 26 December 2007 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 15-19 and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mitchell *et al.* (US 2001/0021835 A1; hereinafter: "Mitchell").

Regarding claims 1 and 19, Mitchell teaches a medical device, comprising:

a flexible body (90), having a proximal end (12);

a distal end (14);

a longitudinal axis; and

a plurality of flexible elongate members (96, 96') defined by an aperture (98, 98')

extending longitudinally in the body (90), the member (96) being radially expandable with respect to the longitudinal axis;

the device defining an eccentric lumen (24), at least a portion of the eccentric lumen (24) being offset from the longitudinal axis (see figures 10, 18 & 19, *infra*).

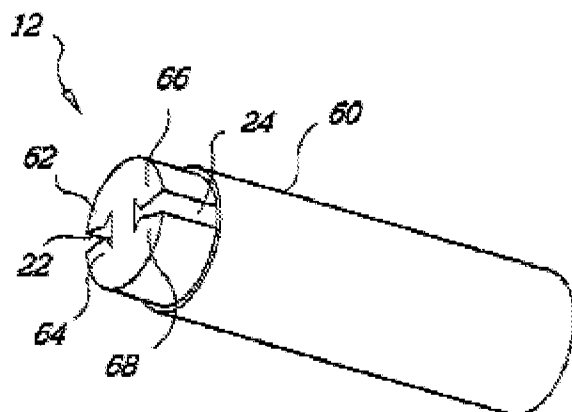


FIG. 10

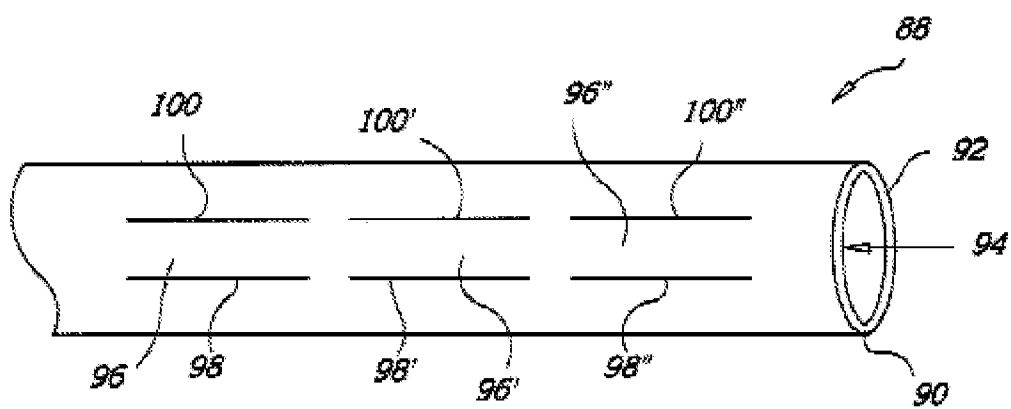


FIG. 18

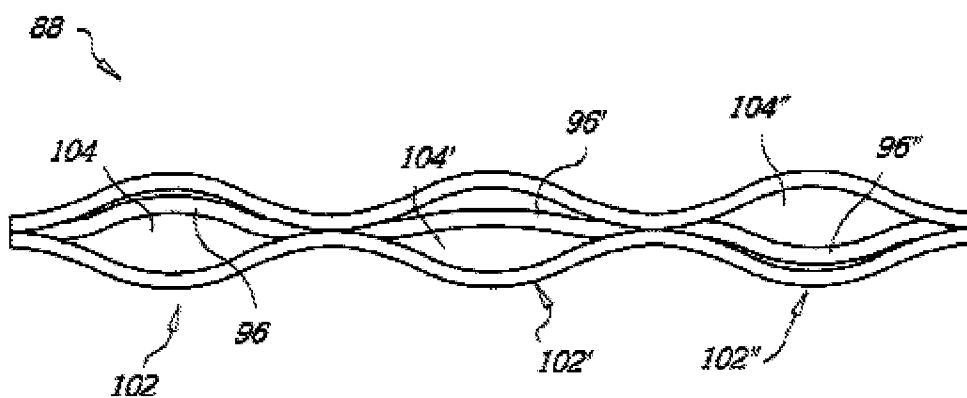


FIG. 19

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Regarding claim 2, see undulations (102) in fig. 19.

Regarding claim 6, see ¶ 0042.

Regarding claim 15, Mitchell teaches a lumen (24) formed of a flexible body member (62) attached to the device.

Regarding claims 16 and 21, Mitchell teaches that the apertures (98) near one of the ends is sealed, see fig. 18.

Regarding claim 17, Mitchell teaches that the sealed portion is openable by displacing guidewire (106).

Regarding claim 18, Mitchell teaches a helical elongate member (see fig. 22, *infra*).



FIG. 22

Claims 1, 3-14, 18, 22 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Beyar *et al.* (US 6,371,979 B1; hereinafter “Beyar”).

Regarding claim 1, Beyar teaches a medical device, comprising:

a flexible body (21), having a proximal end;

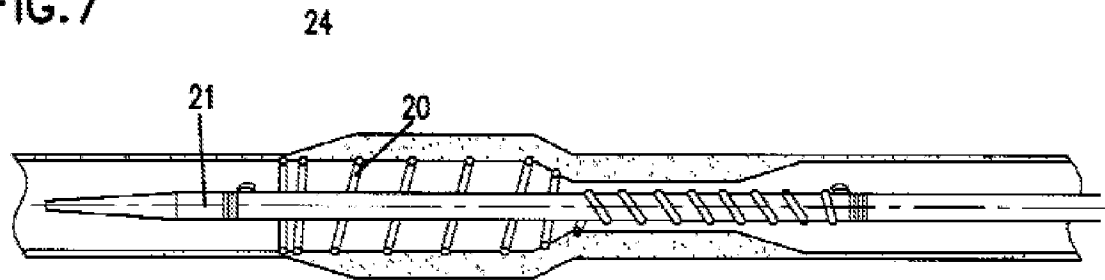
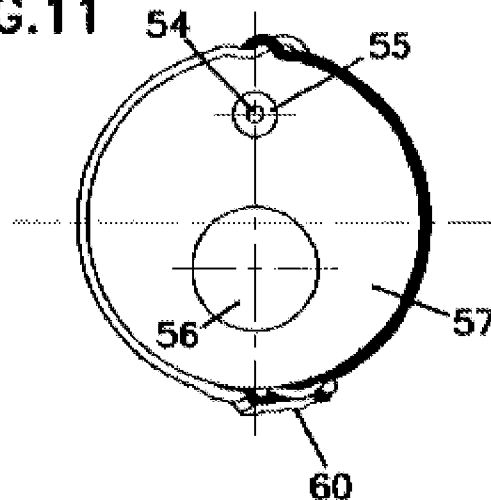
a distal end;

a longitudinal axis; and

a flexible elongate members (20) defined by an aperture (56, center of coil) extending longitudinally in the body (21), the member (20) being radially expandable with respect to the longitudinal axis;

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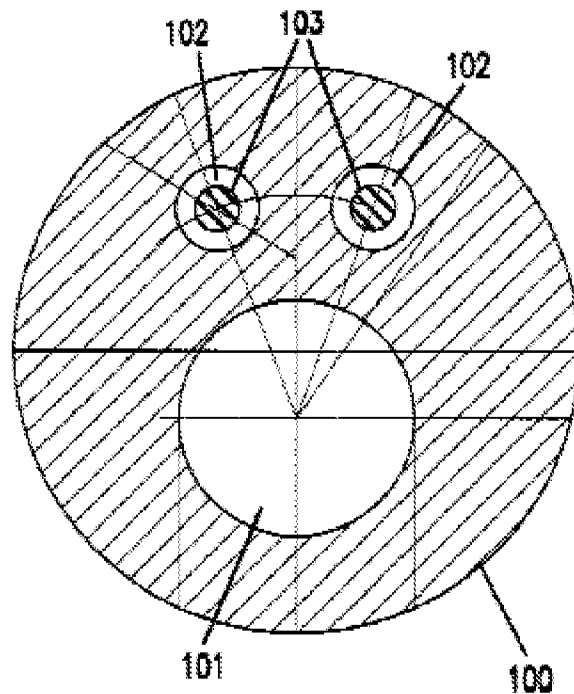
the device defining an eccentric lumen (55), at least a portion of the eccentric lumen (55) being offset from the longitudinal axis (see figures 7 & 11, infra).

**FIG.7****FIG.11**

Regarding claim 3, Beyar teaches that eccentric lumen (55) is within the periphery of the elongate member (20).

Regarding claims 4, 11, 12, 14 and 22, Beyar teaches multiple perforations or lumens/tubes (102) with an insert /tool (103) therein (fig. 17).

**FIG. 17**



Regarding claim 5, Beyar teaches a release wire (103) to transition between unexpanded and expanded states.

Regarding claim 6, Beyar teaches that the device is bioabsorbable (col. 5, line 58-col. 6, line 19).

Regarding claims 7-10 and 13, Beyar teaches a stiffener/guidewire (103) in one or more eccentric lumens (102) at an end of the device that permits the device to convert to an unexpanded state.

Regarding claim 18, Beyar teaches that member (20) is disposed helically (fig. 7).

Regarding claim 23, Beyar teaches polyurethane construction (col. 4, line 16).

***Claim Rejections – 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 20 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Beyar in view of Buscemi *et al.* (US 5,464,450 A; hereinafter “Buscemi”).

Beyar does not disclose expressly a therapeutic agent or barium.



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Buscemi teaches that radiopaque materials such as barium are desirable in stents so that they can be located within a human body. Buscemi also teaches that incorporating therapeutic materials in such devices is desirable (col. 2, lines 1-52).

Where a claimed improvement on a device or apparatus is no more than "the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement," the claim is unpatentable under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d 1509, 1518-19 (BPAI, 2007)(citing *KSR v. Teleflex*, 127 S.Ct. 1727, 1740, 82 USPQ2d 1385, 1396 (2007)). Accordingly, Applicant claims a combination that only unites old elements with no change in the respective functions of those old elements, and the combination of those elements yields predictable results; absent persuasive evidence that the modifications necessary to effect the combination of elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a). *Ex Parte Smith*, 83 USPQ.2d at 1518-19 (BPAI, 2007)(citing *KSR*, 127 S.Ct. at 1740, 82 USPQ2d at 1396). Accordingly, since the applicant[s] have submitted no persuasive evidence that the combination of the above elements is uniquely challenging or difficult for one of ordinary skill in the art, the claim is unpatentable as obvious under 35 U.S.C. § 103(a) because it is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for improvement.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Bogart/  
Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761

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